



UNITED STATES PATENT AND TRADEMARK OFFICE

CPM
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/079,111 | 02/20/2002 | Susan G. Stuart | PC-0053 CIP | 6385 |

27904 7590 07/01/2004
INCYTE CORPORATION
EXPERIMENTAL STATION
ROUTE 141 & HENRY CLAY ROAD
BLDG. E336
WILMINGTON, DE 19880

| |
|--------------------------|
| EXAMINER |
| SWITZER, JULIET CAROLINE |

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1634 | |

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|-------------------|--------------|---------------|
| Application No. | 10/079,111 | Applicant(s) | STUART ET AL. |
| Examiner | Juliet C. Switzer | Art Unit | 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to nucleic acids, vectors, host cells and methods for culturing proteins, classified in class 536, subclass 23.1, for example.
 - II. Claims 7-10, drawn to methods of detection utilizing hybridization, classified in class 435, subclass 6.
 - III. Claims 11-12, drawn to methods for screening molecules or compounds, classified in class 435, subclass 6.
 - IV. Claims 13-15, drawn to isolated polypeptides, classified in class 530, subclass 300.
 - V. Claims 16-17, drawn to methods for screening using polypeptide binding, classified in class 435, subclass 7.1.
 - VI. Claims 18-20, drawn to antibodies and methods of making antibodies, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II and inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used in a

variety of methods including for expression of an encoded polypeptide, detection assays, nucleic acid purification assays, aptamer methods, etc.

3. Inventions I, IV, and VI are patentably distinct in structure and physiochemical properties. Invention I is drawn to nucleic acids and constructs comprising nucleic acids whereas invention II is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. The antibody of Group VI is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be used in ligand binding assays or to generate antibodies, and antibodies can be used in immunoassay. Synthesis of the proteins of invention IV do not require the particular nucleic acids of invention I since the proteins of invention IV can be isolated from natural sources or chemically synthesized. Although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein as evidenced by the methods of at least groups II and III.

4. Inventions I and V are unrelated. Inventions II and III are unrelated to invention IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as used together as the polynucleotides of invention I are not used in the screening methods of invention V. Likewise, the polypeptides of invention III are not used in the methods for detecting expression of invention II or the screening methods of invention III.

5. The methods of inventions II, III, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions are drawn to methods which are not disclosed as used together and which have separate goals, method steps and utilize different modes of operation.

The methods of detecting expression of invention II utilize a nucleic acid hybridization step for the purpose of assaying a sample for the expression of a particular nucleic acid. The methods of invention III, however, differ from this method as they are directed towards screening compounds to discover ones that bind to the nucleic acid, while the methods of invention V are drawn to screening for ligands to a polypeptide. The methods of invention V are drawn to the making of antibodies and utilize the immunization of animals, for example.

6. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention IV can be used in screening methods, to raise antibodies, for the production of fusion proteins, etc.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their classification and recognized divergent subject matter and because inventions I-VI require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. A telephone restriction requirement was not made in this application due to an explicit request by Incyte and their policy of not making elections in response to telephonic restriction requirements.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached by calling (571) 272-0782.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Juliet C. Switzer
Examiner
Art Unit 1634

June 25, 2004